

French National Agency for Medicines and Health Products Safety

CERTIFICATE NUMBER: **15MPP042HFR01**

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER ^{1, 2}

Part 1

Issued following an inspection in accordance with :
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of France confirms the following:
The manufacturer: **ESCO France - DOMBASLE-SUR-MEURTHE**
Site address: **ZA Solvay Porte Est, route des Dignes, DOMBASLE-SUR-MEURTHE, 54110, France**

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC transposed in the following national legislation:
Set of regulation L.5138-1 to -5 of Public Health Code

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2015-04-23**, it is considered that it complies with :

- The principles of GMP for active substances ³ referred to in Article 47 of Directive 2001/83/EC .

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in EudraGMP. If it does not appear, please contact the issuing authority.

¹ The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.

² Guidance on the interpretation of this template can be found in the Help menu of EudraGMP database.

³ These requirements fulfil the GMP recommendations of WHO.

**"VALABLE UNIQUEMENT
POUR L'ÉTRANGER"**

Copie certifiée conforme à l'original
qui nous a été présenté,
Levallois-Perret, le 28.12.2015
Pour le Maire,
L'Officier de l'Etat-Civil délégué
Mr Anne CELONG



Part 2

Manufacture of active substance. Names of substances subject to inspection :

SODIUM CHLORIDE(en) / **SODIUM (CHLORURE DE)**(fr)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES	
Active Substance : SODIUM CHLORIDE	
3.2	Extraction of Active Substance from Natural Sources
	3.2.4 Extraction of substance from mineral source
3.5	General Finishing Steps
	3.5.1 Physical processing steps : Sieving
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)

Clarifying remarks (for public users)

Quality Control activities are outsourced

2015-07-09

Name and signature of the authorised person of the
Competent Authority of France

Le chef du pôle Inspection des matières premières
Direction de l'inspection



Guillaume RENAUD

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